IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

BLANE NEWMAN, a minor, by and through his father and stepmother and natural guardians, GARY NEWMAN and DEBRA NEWMAN, and MARIAM KHAWAM,	)	**No. 10 C 1541**
	)	**Magistrate Judge Maria Valdez**
Plaintiffs,	)	
v.	)	
MCNEIL CONSUMER HEALTHCARE, a division of MCNEIL-PPC, INC., and JOHNSON & JOHNSON,	)	
Defendants.	)	

ORDER

This matter is before the Court on Defendants' and Plaintiffs' motions for summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure. [Doc. Nos. 188, 197.] The parties have consented to the jurisdiction of the United States Magistrate Judge pursuant to 28 U.S.C. § 636(c). For the reasons set forth below, Defendants' motion for summary judgment is granted in part and denied in part; and Plaintiffs' motion for summary judgment is granted in part and denied in part.

FACTS[1]

Defendant Johnson & Johnson is a New Jersey Corporation. [Doc. No. 189 ¶ 2.] Defendant McNeil Consumer Healthcare ("McNeil") is a division of McNeil-PPC, Inc., a New Jersey Corporation. [*Id.* ¶ 1.] McNeil manufactures and markets Motrin products. [*Id.*] Motrin is an over-the-counter ("OTC") medication whose active ingredient is ibuprofen, a nonsteroidal anti-inflammatory drug ("NSAID") derived from propionic acid. [Doc. No. 124 ¶ 5.] Ibuprofen is widely used to treat pain, inflammation, and fever, with billions of doses sold worldwide. [*Id.*] The Food and Drug Administration ("FDA") approved ibuprofen for adult prescription use in 1974, and for adult OTC use in 1984. [*Id.* ¶ 6.] The FDA approved a prescription version of Children's Motrin in 1989, and approved an OTC version of Children's Motrin in 1995. [*Id.*]

Stevens-Johnson Syndrome ("SJS") is a rare and unpredictable skin disease. [*Id.* ¶ 8.] Toxic Epidermal Necrolysis ("TEN") is even rarer.[2] SJS and TEN are acute, life-threatening conditions involving extensive skin detachment and erosion

[1] Unless otherwise noted, the following material facts are either undisputed or deemed admitted due to a party's failure to comply with Local Rule 56.1, which this Court strictly enforces. *See Smith v. Lamz*, 321 F.3d 680, 683 (7th Cir. 2003); *Malec v. Sanford*, 191 F.R.D. 581, 583-84 (N.D. Ill. 2000). The following events are recounted in the light most favorable to the nonmovant, with relevant disputes noted. *See Sow v. Fortville Police Dep't*, 636 F.3d 293, 299–300 (7th Cir. 2011).

[2] The incidence of these diseases is disputed by the parties. For SJS, Defendants report an estimated incidence of one to two cases of SJS/TEN per million persons per year from all causes. [Doc. No. 189 ¶ 15.] Plaintiff argues that the actual incidence of SJS and TEN cases is not firmly established, and could be as high as forty-nine to sixty cases per million. [Doc. No. 207, at 5-6.]

of the mucosal tissue. [Doc. No. 133, at 24-25.] TEN is the more severe form, characterized by skin detachment affecting more than thirty percent of the total body surface area. [*Id.*] Since 1983, McNeil's labeling for its prescription Motrin products has listed SJS as having a "probable causal relationship" with ibuprofen. [*Id.* at 25.] Since 2006, the FDA has required McNeil to expressly state on its prescription Motrin label that "NSAIDs, including Motrin [ ], can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson Syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal." [*Id.*]

Medical researchers have conducted two large case-control studies to determine which drugs might pose risks of triggering SJS/TEN. [Doc. No. 207, at 8.] The results of the first case control study, the epidemiological study on severe cutaneous adverse reactions ("SCAR"), was conducted between 1989 and 1995, and the results were reported in papers published in 1995 and 2003. [*Id.*] The authors of the 1995 article found an increased risk for SJS/TEN in persons taking propianic acid NSAIDS (which include ibuprofen) for less than two months. [*Id.* at 8-9.] The 2003 article analyzed the study's full data set and reported a statistically significant association between SJS/TEN and ibuprofen. [*Id.* at 8.] The second and most recent study, the EUROSCAR study, ascertained cases and control prospectively from a network that covered a population of more than 100 million people between 1997 and 2001. [*Id.* at 9-10.] The EUROSCAR study was reported in

a peer-reviewed paper published in 2008, and the authors of the paper reported that ibuprofen does not increase the risk of SJS/TEN. [*Id.*]

On February 15, 2005, a Citizen Petition was submitted to the FDA. [Doc. No. 124 ¶ 39.] In it, petitioners requested that a full risk assessment of SJS and TEN associated with ibuprofen be conducted by the FDA; that the FDA require the manufacturers of ibuprofen to amplify their prescription and OTC labeling to adequately warn prescribers, health care professionals and consumers of the increased risk of SJS and TEN associated with ibuprofen; and that the FDA require the manufacturers to provide to physicians and consumers instructions to discontinue all ibuprofen products at the first sign of a rash, mucosal blisters, or sores in the mouth, eyes, throat, or genitalia, and any unexplained or persistent fever. Citizen Petition to Request Risk Assessment of SJS and TEN, at 1-2 (Feb. 15, 2005) (Hereinafter "Citizen Petition"). The Petition also requested that the FDA withdraw approval of OTC ibuprofen products such as Motrin, and alleged that OTC ibuprofen manufacturers, including McNeil, had misled the FDA in obtaining approval for OTC ibuprofen and its label. [Doc. No. 124 ¶ 41.]

On June 22, 2006, the FDA responded to the Citizen Petition.[3] [*Id.* ¶ 43.] The FDA stated that the agency had "engaged in a comprehensive review of the risks

[3] Between the time the Citizen Petition was submitted and the FDA responded, the FDA directed all NSAID manufacturers to include new warnings with regard to several potential risks. As pertains to SJS and TEN, the FDA required the labeling for OTC NSAIDs be revised to include a description of early symptoms associated with SJS. [Doc. No. 124 ¶ 38.]

and benefits, including the risks of SJS and TEN, of all approved NSAID products, including ibuprofen." [*Id.*] The FDA also reviewed other available evidence on the incidence of SJS and TEN, "including review of clinical trials submitted to FDA for marketing approvals, review of other clinical studies available in the scientific literature, and review of the Adverse Event Reporting Systems (AERS) surveillance database." [*Id.*] In its response, the FDA concluded that "the overall benefit versus risk profile for ibuprofen products remains very favorable when they are used according to the labeled instructions" and rejected the petitioners' request that the agency revoke OTC approval of ibuprofen products. [*Id.* ¶ 44.] The FDA refused to require the petitioners' proposed warning, and specifically declined to require that manufacturers include references to SJS and TEN in OTC ibuprofen labels. [*Id.* ¶ 47.] The FDA noted that adding easily identifiable references to the symptoms associated with SJS and TEN (*e.g.*, skin reddening, rash and blisters) under the "allergy alert" subheading and including a warning that instructed consumers to stop use and seek medical help right away if an allergic reaction occurs would alert and educate consumers about the nature of the reaction associated with SJS and TEN. [*Id.* ¶ 48.]

When the FDA responded to the Citizen Petition, it noted that a search of the U.S. adverse event report database showed that there had been 49 reports of SJS/TEN related to ibuprofen from 1975 through March 2005. [Doc. No. 133, at 34.] The FDA thought that there had been "no notable trend over the years." [*Id.*] Since

that time, McNeil has continued to receive adverse event reports ("AERs") regarding ibuprofen-related SJS/TEN cases. [*Id.*] In response to Plaintiffs' discovery request in this case for AERs that McNeil received from 2005 to the present, McNeil produced 117 AERs of ibuprofen-related SJS/TEN cases. [*Id.* at 35.] Eighty-seven of those AERs were received by McNeil prior to June 2009. [*Id.*][4]

Plaintiffs assert that Mariam Khawam's ("Mariam") and Blane Newman's ("Blane") use of Motrin in the summer of 2009 caused each of them to develop SJS and/or TEN. [Doc. No. 124 ¶ 15.] Blane's allegations pertain to OTC Children's Motrin, while Mariam's allegations pertain to OTC Motrin IB; both OTC Children's Motrin and OTC Motrin IB have the same active ingredient and include materially identical labels.[5] [*Id.*] On June 25, 2009, Mariam's mother, Anna Khawam, gave her a dose of Motrin to treat a fever; Mariam was given at least two more doses that day to treat the fever. [*Id.* ¶ 19.] The next day, Mariam's fever had reached 103.5 degrees, her eyes were bloodshot, and she had lumps in her throat. [*Id.*] Mariam's pediatrician recommended that she continue taking Motrin at double the recommended dosage while her fever remained high. [*Id.* ¶ 20.] Mariam's fever

[4] AERs forms Bates numbered LFR01319290-LFR01319435 contain reports created from January 1, 2005 through June 7, 2011. There are 117 report forms contained in this Bates range. Defendants maintain that many of the report forms are duplicate reports for a single adverse event. Defendants assert that once duplicates are accounted for, there are 97 unique individual adverse events. [Doc. No. 189 ¶ 42.] Of these 97 adverse events, Defendants claim that no more than 83 of them were reported to McNeil between June 2005 and June 2011. (Id. ¶ 46.)

[5] Accordingly, unless stated otherwise, the term "Motrin" will be used to refer to both Children's Motrin and Motrin IB.

continued to rise and she developed a small rash on her abdomen; on the morning of June 27, Mariam's temperature reached 104 degrees and the rash spread to her arms and back. [*Id.*] By the morning of June 28, Mariam's skin had started to blister. [*Id.* ¶ 21.] She was given another dose of Motrin and taken to the emergency room where she was diagnosed with SJS/TEN. [*Id.*] Mariam has suffered serious and ongoing injuries as a result of the disease. [*Id.*]

On July 6, 2009, Blane's stepmother, Debra Newman, gave him a dose of Motrin to treat a fever. [*Id.* ¶ 24.] Blane took several more doses of Motrin the next day but remained feverish and continued to feel unwell. [*Id.*] By the afternoon of July 7, Blane's stepmother noted that he had developed reddish bumps on the back of his neck, and that his eyes were watery and glossy. [Doc. No. 204 ¶ 1.] Debra Newman gave him another dose of Motrin. [*Id.*] By that evening, he had more bumps on his back and the bumps spread to Blane's upper body, back, chest, face, arms and neck by July 8. [Doc. No. 124 ¶ 24.] Blane's stepmother decided to stop giving Blane further doses of Motrin and took him to the doctor's office. [*Id.*] There, a nurse practitioner diagnosed Blane with a severe reaction to poison ivy and recommended that he continue to take Motrin, along with Benadryl and a steroid. [*Id.*] Blane's symptoms continued to worsen and by July 9, the bumps had turned to blisters, which had spread to other parts of his body. [*Id.* ¶ 26.] Blane's stepmother took him to the emergency room later that day, and the ER doctor who saw Blane suspected SJS and transferred him to Loyola University Medical Center, where he

was diagnosed with SJS/TEN. [*Id.*; Doc. No. 133, at 26-27.] Blane has suffered serious and ongoing injuries as a result of the disease. [Doc. No. 124 ¶ 26.]

In June and July of 2009, the label for Motrin provided as follows:

> **WARNINGS:**
>
> ***Allergy Alert***: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
>
> - hives
> - facial swelling
> - asthma (wheezing)
> - shock
> - skin reddening
> - rash
> - blisters
>
> If an allergic reaction occurs, stop use and seek medical help right away [ ]
>
> ***Stop use and ask a doctor if***
>
> - you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
> - pain gets worse or lasts more than 10 days
> - fever gets worse or lasts more than 3 days
> - stomach pain or upset gets worse or lasts
> - redness or swelling is present in the painful area
> - any new symptoms appear

[*Id.* ¶ 36.] This warning language has not changed in the years since Blane and Mariam consumed Motrin, and these were the warnings on the labels of the products Blane and Mariam used. [*Id.*]

Plaintiffs maintain that Motrin caused Blane's and Mariam's injuries, that the drug was negligently designed, and that it included improper warnings. [*Id.* ¶ 27.] Plaintiffs' Second Amended Complaint ("Complaint") alleges claims for

defective design, failure to warn, negligence, consumer fraud, breach of express warranty of fitness, breach of implied warranty of fitness, and willful and wanton misconduct. [*Id.* ¶ 4.] In Defendants' Amended Answer to Plaintiffs' Second Amended Complaint ("Answer"), Defendants' assert a variety of affirmative defenses, including contributory negligence and assumption of risk. [Doc. No. 75, at 20-21; Doc. No. 76, at 20-21.] Defendant now moves for summary judgment on all of Plaintiffs' claims, and Plaintiff moves for summary judgment on Defendants' affirmative defenses of contributory negligence and assumption of risk. [Doc. Nos. 188, 197.]

DISCUSSION

A. Summary Judgment Standard

Summary judgment is appropriate where "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The Court must draw all reasonable inferences in favor of the nonmovant. *Bennington v. Caterpillar Inc.,* 275 F.3d 654, 658 (7th Cir. 2001).

However, once the movant has carried its burden under Rule 56(c), "its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586 (1986). The party opposing summary judgment must offer admissible evidence in support of his version of events, and hearsay evidence does not create a

genuine issue of material fact. *McKenzie v. Ill. Dep't of Transp.,* 92 F.3d 473, 484 (7th Cir. 1996); *see Larimer v. Dayton Hudson Corp.*, 137 F.3d 497, 500 (7th Cir. 1998) ("'If the non-moving party bears the burden of proof on an issue, . . . that party may not rest on the pleadings and must instead show that there is a genuine issue of material fact.'") (citation omitted). "The mere existence of an alleged factual dispute is not sufficient to defeat a summary judgment motion. . . . The nonmovant will successfully oppose summary judgment only when it presents 'definite, competent evidence to rebut the motion.'" *Vukadinovich v. Bd. of Sch. Trs. of N. Newton Sch. Corp.*, 278 F.3d 693, 699 (7th Cir. 2002) (citations omitted).

"In considering a motion for summary judgment, this court is not required to scour the record in search of evidence to defeat the motion; the nonmoving party must identify with reasonable particularity the evidence upon which the party relies." *Pleniceanu v. Brown Printing Co.*, No. 05 C 5675, 2007 WL 781726, at *7 (N.D. Ill. Mar. 12, 2007) (citing *Johnson v. Cambridge Indus., Inc.,* 325 F.3d 892, 898 (7th Cir. 2003)); *see also Estate of Moreland v. Dieter*, 395 F.3d 747, 759 (7th Cir. 2005) ("We will not scour a record to locate evidence supporting a party's legal argument."); *Knapp v. County of Jefferson*, No. 06 CV 4028, 2007 WL 496396, at *1 (S.D. Ill. Feb. 13, 2007) (denying summary judgment where defendant's brief "contains no facts section and . . . fail[s] to point to the relevant portions of the record to establish the facts of this case").

B. Defendants' Motion for Summary Judgment

Defendants previously moved for summary judgment of Plaintiffs' claims on the basis of federal preemption. [Doc. No. 121.] That motion was denied. [Doc. No. 163.] In this motion, Defendants move for summary judgment on each of Plaintiffs' claims on other grounds based on Illinois law.

1. Plaintiffs' Consumer Fraud Claim (Count IV)

In order for Plaintiffs to prevail on their claims under the Illinois Consumer Fraud Act ("CFA"), they must show the following: (1) a deceptive act or practice by defendant; (2) the defendant's intent that plaintiff rely on the deception; and (3) the occurrence of the deception in a course of conduct involving trade or commerce; (4) actual damage to the plaintiff that is (5) a result of the deception. *De Bouse v. Bayer*, 922 N.E.2d 309, 314 (Ill. 2009) (citing *Zekman v. Direct Am. Marketers, Inc.*, 695 N.E.2d 853 (Ill. 1998)). Even if a plaintiff meets these requirements, Section 10b(1) of the CFA provides that nothing in the Act shall apply to "[a]ctions or transactions specifically authorized by laws administered by any regulatory body or officer acting under statutory authority of this State of the United States." 815 ILCS. 505/10b(1). In interpreting the statute, the Illinois Supreme Court has held that if the statements or omissions at issue have been "specifically authorized by the [agency] in the course of carrying out the duties assigned to it by Congress, [the]

action cannot stand, even if the [statements or omissions] might be found deceptive by a trier of fact." *Price v. Philip Morris*, 848 N.E.2d 1, 33 (Ill. 2005).[6]

Plaintiffs maintain that there are two bases for the inapplicability of the defense: (1) that the Defendants 2005 standby statement was deceptive; and (2) that the Defendants' conduct was not in compliance with the FDA regulations requiring it to analyze any newly discovered safety data and submit an update to warn of the newly discovered danger.

a. Deceptive Statement

Plaintiffs assert that the "standby statement"[7] issued by the Defendants in 2005 intentionally omitted the known causal relationship between ibuprofen and SJS/TEN. The deception, they argue, was that it omitted information known to McNeil, as acknowledged in their 2003 standby statement which explained that SJS and TEN are serious skin reactions that are associated with the use of medications. [Doc. No. 208-47, at 2; Doc. No. 208-48, at 1.] Plaintiff maintains that "[t]his deceptive statement, intended for public consumption, was certainly not 'specifically authorized' by the FDA," and thus, is not subject to the statutory exception of the CFA.

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[6] Similarly, if the statements or omissions at issue have been used by a defendant in compliance with the orders or rules of the federal agency, an action under the Deceptive Practices Act is also barred. *Price*, 848 N.E.2d at 33.

[7] Plaintiffs explain that a standby statement is "essentially a press release that provides health information in response to a particular issue." (Pls.' Resp. at 38.)

According to the Plaintiffs the deception in the statement was the substantial watering down of the language used in the 2005 statement from the original 2003 statement. The relevant portions of the 2003 statement said more about the specific causal relationship between ibuprofen ans SJS/TEN:

> McNeil Consumer Speciality Pharmaceuticals is aware of a report of a 9 year-old girl from California who has been diagnosed with Stevens-Johnson Syndrome or toxic epidermal necrolysis allegedly associated with the use of Children's Motrin. As the manufacturer of Motrin ibuprofen products, we are deeply concerned about all matters relating to our products and are investigating this incident.
>
> Stevens-Johnson Syndrome and toxic epidermal necrolysis are serious skin reactions that are often associated with the use of medications. There are several medications that are associated with these skin reactions, including ibuprofen, the active ingredient in Children's Motrin products.

[Doc. No. 208-47, at 2.]

The relevant portions of the 2005 statement reads as follows:

> McNeil Consumer & Speciality Pharmaceuticals is aware of a report of a 7 year-old girl who has been diagnosed with Stevens-Johnson Syndrome, allegedly associated with the use of Children's Motrin.
>
> Stevens-Johnson Syndrome is a very rare condition. While the specific causes of the condition in any given instance is unknown, it has been reported to be associated with a wide variety of medications and may also be caused by viral infections.

[Doc. No. 208-48, at 1].

The first statement offered an association between SJS and the use of Motrin. The 2005 statement offered that this association only as "alleged." Even so, Plaintiffs have not shown that the 2005 statement is inaccurate. The 2005 statement is consistent with the FDA-approved Motrin labels and is not "so

misleading or deceptive in the context that federal law itself might not regard [it] as adequate."*Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001).

b. Compliance with Federal Law

Even if the materials that Plaintiffs identify were deceptive, the Court could find the statutory exemption applicable if the materials were nevertheless in compliance with governing FDA regulations. "The question is thus whether the statements [the plaintiff] complains of are sufficiently within what is authorized by federal law that [the defendant] is entitled to section 10b(1) protection."*Bober,* at 941; *see also Price v. Philip Morris, Inc.*, 848 N.E.2d 1, 41 (2005).

Plaintiffs argue that the evidence "shows that Defendants' conduct is not in compliance with FDA regulations requiring it [*sic*] to analyze newly acquired safety data and submit an appropriate update to its warning label regarding risks as soon as a causal association with its drug is shown." (Pls.' Resp. at 39.) According to Plaintiffs, such noncompliance taints any "specific authorization" by the FDA and, at the very least, makes the applicability of the CFA exception a question of material fact that the jury must resolve.

In support of their position, Plaintiffs cite to Dr. Plunkett's Report for Blane Newman,[8] the deposition testimony of Lynn Pawleski, and the deposition testimony of Dr. Kuffner, as well as 21 C.F.R. §§ 201.57, 314.70, and 314.81. (Pls.' Resp. at

[8] This Court, under separate order, has barred Dr. Plunkett's testimony on this issue pursuant to the *Daubert* analysis. The Court, nonetheless, addresses the testimony and determines that is remains unhelpful.

39.)[9] In the cited portions of her report, Dr. Plunkett explains that "manufacturers always have the ability under the current FDA regulations to update their labeling in order to strengthen warnings," (Plunkett's Report, ¶ 33 [Doc. No. 136-1]), and that "review of depositions and testimony of company employees . . . and consultants to McNeil . . . revealed that McNeil was aware of and admitted to reports and literature regarding SJS and TEN associated with ibuprofen . . . and yet never performed [the] analysis [required by the regulations]." (*Id.* ¶ 43.) Dr. Plunkett also asserts that McNeil "failed to properly submit to FDA the [2003 Mockenhaupt *et al.* article regarding SCAR] that specifically linked ibuprofen to SJS and TEN" by "submitting to FDA only the abstract of the 2003 paper." (*Id.*)

Dr. Plunkett's assertions do not constitute evidence of Defendants' noncompliance. First, as an initial matter, Dr. Plunkett's conclusions concerning the testimony of Defendants' employees and consultants on the subject of McNeil's noncompliance constitutes analysis that is at least one step removed from the

[9] "Labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug." 21 C.F.R. § 201.57(c)(6)(i). The holder of an approved application may "add or strengthen a contraindication, warning, precaution, or adverse reaction for which the evidence of a causal association satisfied the standard for inclusion in the labeling under § 201.57" without receiving prior approval from the FDA for such a change. 21 C.F.R. § 314.70(c)(6)(iii)(A). And the applicant must submit an annual report that includes "[a] brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product," "a brief description of actions the applicant has taken or intends to take as a result of this new information," "[p]ublished clinical trials of the drug (or abstracts of them)," "[a]nalysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information," and "[s]tatus reports of postmarketing study commitments." 21 C.F.R. § 314.81(b)(2).

evidence on which Plaintiffs should be relying. That is, if the testimony of company employees and consultants reveals Defendants' noncompliance, Plaintiff should demonstrate that with testimony. Second, Dr. Plunkett's claim that McNeil improperly submitted the 2003 Mockenhaupt *et al.* data is irrelevant even if it is accurate: the FDA's Response indicates that it considered the 2003 Mockenhaupt *et al.* data in its decision; therefore, assuming there was any noncompliance, it did not taint the agency's "specific authorization." (FDA Resp. at 3.)

And finally, Dr. Plunkett's deposition testimony undermines the assertions she makes in her report. In her *report*, Dr. Plunkett states:

> As stipulated in § 314.80 of the Federal Regulations, manufacturers like McNeil "shall promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source . . . [a]ny person subject to the reporting requirements . . . shall also develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA . . . [e]ach periodic report is required to contain: (a) a narrative summary and analysis of the information in the report."

(Plunkett's Report ¶ 43) (quoting 21 C.F.R. § 314.80). However, in her *deposition*, with regard to Defendants' noncompliance, Dr. Plunkett testified that she was not asserting that they failed to submit a particular report at a particular period of time. (Plunkett Dep. at 190:8-9.) In an attempt to buttress her position, she explained that "going back to Dr. Temple's testimony and him stating that the company did no analysis of those reports, based upon that, it's – it's – it's my opinion that if you look at the regulations, that the regulations continually talk

about reporting and what needs to be done." (*Id.* at 191:9-14.) The court has scoured Dr. Temple's deposition testimony and has not been able to identify any testimony by Dr. Temple that may be reasonably interpreted as an admission that McNeil failed to perform any required analysis on any reports during the time that McNeil was obligated to do so by FDA regulations. (*See generally* Temple Dep. [Doc. No. 208-15].) The context of Dr. Plunkett's deposition testimony suggests that she may have been referring to two AERs that McNeil became aware of in the early 1980s. (*See* Plunkett Dep. at 192:3-13; Temple Dep. at 52:21- 53:15.) However, McNeil had no obligation to perform an analysis on those 1980s reports. (Temple Dep. at 63:14 - 64:14). Plaintiffs have offered no evidence that the FDA failed to consider those two AERs (or any AERs available at the time) when it responded to the Citizen Petition in 2006.

The cited portion of Ms. Pawelski's deposition is similarly unhelpful to Plaintiffs. The brief bit of testimony by Ms. Pawelski fails to constitute evidence of Defendants' noncompliance. (Pawelski Dep. at 68:10-16 [Doc. No. 134-17].) The content of Dr. Kuffner's deposition also fails to provide evidence that Defendants' conduct has not been in compliance with FDA regulations. Dr. Kuffner's testimony indicates that McNeil "saw the apparent increase in the number of [AERs] and then did an analysis to try to better understand all of those cases," and that following the analysis, McNeil "did not detect a new safety signal related to the increased number of [AERs.]" (Kuffner Dep. at 67:23-68:19 [Doc. No. 208-56].) The other portion of Dr.

Kuffner's deposition that Plaintiffs cite was not a part of the exhibit that Plaintiffs filed, and the Court could not evaluate it.[10]

Notably, in its response to the Citizen Petition, the FDA addressed allegations of noncompliance by ibuprofen manufacturers:

> You state that manufacturers of ibuprofen drug products have withheld safety information regarding the risks of SJS and TEN associated with ibuprofen products and request FDA to conduct an investigation accordingly. You state that "McNeil and Wyeth have failed to provide the FDA full information regarding the safety issues surrounding serious skin reactions, including SJS/TEN that were not presented in their applications for their OTC pediatric formulations" (Petition at 9). However, you provide no evidence to support this allegation. In addition, we have no evidence that there is additional undisclosed safety information that was withheld by ibuprofen manufacturers. If you have any information to support this allegation, please provide it to us.

(FDA Resp. at 6.)

Plaintiffs argue that the authors of the Citizen Petition were barred from disclosing information regarding noncompliance under the terms of confidentiality orders governing SJS/TEN litigation in which they were involved, [Doc. No. 207 at 33], but this does not excuse Plaintiffs' obligation to provide evidence of their claim.

Plaintiffs' evidence of Defendants' noncompliance with FDA regulations is slight, at best. But the Court need not decide whether a reasonable jury could

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[10] Dr. Kuffner's deposition was included as Exhibit CCC to David Greenstone's Declaration regarding Plaintiffs' memorandum in opposition to Defendants' motion for summary judgment. [Doc. No. 208-56.] In support of the proposition that Defendants' conduct is not in compliance with FDA regulations, Plaintiffs cite pages 64-66 and 73 of Dr. Kuffner's deposition. The exhibit includes pages 62-69 and 74-77, but omits pages 70-73.

determine that Defendants failed to comply with any FDA regulations, however, because even if a jury could so find, Plaintiffs have offered no evidence that the noncompliance at issue affected the FDA's determinations and "specific authorization." Plaintiffs' theory–as it has been generously interpreted–is that the FDA's specific authorization is inconsequential because the agency lacked or lacks vital information due to Defendants' noncompliance. Therefore, Plaintiffs are obligated to provide evidence of noncompliance *and* explain how such noncompliance affected or is currently affecting the FDA's decision making. Plaintiffs vaguely assert that "the FDA is not fully aware of the most current information regarding the risk of SJS/TEN from ibuprofen." (Pls.' Resp. at 23.) Plaintiffs have failed to do so. Therefore, summary judgment is granted to Defendants on Plaintiffs' consumer fraud claim.

2. Plaintiffs' Express Warranty Claim (Count V)

To prove an express warranty claim, a plaintiff must show that a product failed to conform with an affirmative statement of fact or promise or an express description of the goods. *Hasek v. DaimlerChrysler Corp.*, 745 N.E.2d 627, 634 (2001). Plaintiff claims that the statement, "Pain Reliever / Fever Reducer" that is present on Defendants' Motrin products, constitutes an express warranty. They say that Defendants breached that warranty because the Motrin products caused Blane and Mariam to experience an increase in their fevers and caused intense pain and severe injuries. (Pls.' Resp. at 40.) Defendants counter that the Motrin labeling made no guarantees as to its safety or efficacy, and argues that the labeling itself

recognizes the limitations of the products by warning of severe allergic reactions, various potential side effects, and the possibility that a user's symptoms may last or actually get worse. Defendants' arguments have more merit.

First, the labeling on Motrin products does not guarantee effectiveness or safety. Plaintiffs focus on "pain reliever/fever reducer" language is more reasonably interpreted as a statement of the *purpose* of the product: in fact on both labels, it says, "Pain reliever/fever reducer" right under the heading, "Purpose." [Doc. No. 191-16, 17.]

Second, even if the statement could be reasonably read as a promise that the drug would relieve pain and reduce fever, it could only be interpreted like that if it were examined in a vacuum: the labeling clearly indicates that use of the Motrin products "may cause a severe allergic reaction." [*Id.*] The labeling also informs users to "Stop use and ask a doctor if . . . pain gets worse or lasts more than 10 days. . . fever gets worse or lasts more than 3 days." [*Id.*] The label for both products informed Plaintiffs that the product might not relieve pain and might not reduce fever. No reasonable jury could determine that Defendants made any actionable express warranties; therefore, summary judgment is granted to Defendants on Plaintiffs' express warranty claim.

3. Plaintiffs' Strict Liability Design Defect Claim and Breach of Implied Warranty Claim (Counts I & VI)

Both parties agree that if Plaintiffs provide evidence such that a reasonable jury could determine that Defendants' Motrin products are "unreasonably

dangerous," then summary judgment should be denied on Plaintiffs' claims of strict liability design defect and breach of implied warranty.[11] Illinois law provides two methods for parties to demonstrate that a product is unreasonably dangerous: the consumer expectations test and the risk-utility test. *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 348 (Ill. 2008). Where the evidence presented "by either or both parties" is "sufficient to implicate the risk-utility test, the broader test, which incorporates the factor of consumer expectations, is to be applied by the finder of fact." *Id.* at 352-53. The parties agree that the evidence in this case is sufficient to implicate the risk-utility test. (Pls.' Resp. at 15; Defs.' Reply at 5.)

Under the risk-utility test, the plaintiff must present evidence "that the magnitude of the danger outweighs the utility of the product, as designed." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 257 (Ill. 2007). The court first balances relevant factors to determine whether the case should be submitted to a jury. *Jablonski v. Ford Motor Co.*, 955 N.E.2d 1138, 1155 (Ill. 2011). If the plaintiff satisfies this threshold determination, "the finder of fact then determines what weight to give any particular factor, with the relevance of the factors varying from

[11] Plaintiffs argue that a claim for breach of implied warranty does not require proof that a product is unreasonably dangerous, but admits that there is a conflict among Illinois appellate courts on the issue. (Pls.' Resp. at 15) (*citing Muller v. Synthes Corp.*, No. 99 C 1492, 2002 WL 460827, at *6 n.11 (N.D. Ill. Mar. 22, 2002)). The Court need not attempt to resolve the apparent conflict because it determines that Plaintiffs have produced evidence such that a reasonable jury could find that Defendants' Motrin products are unreasonably dangerous.

case to case." *Sosnowski v. Wright Med. Tech. Inc.*, No 11 C 0059, 2012 WL 1030485, at *2 (N.D. Ill. Mar. 27, 2012) (citing *Jablonski*, 955 N.E.2d at 1155). The broad range of factors to be considered include: (1) the product's utility to the user and to the public as a whole; (2) the likelihood that the product will cause injury and the probable seriousness of the injury; (3) the product's compliance with design standards in the industry, design guidelines provided by an authoritative voluntary organization, or design criteria set by legislation or governmental regulation; (4) the instructions and warnings accompanying the product; (5) the availability and feasibility of alternative designs at the time the product at issue was manufactured; and (6) consumer expectations. *Sosnowski*, 2012 WL 1030485, at *2 (citing *Mikolajczyk*, 901 N.E.2d at 335, 352; *Calles*, 864 N.E.2d at 260). A plaintiff is not required to show proof on each or any specific factor, but "evidence on at least one factor is needed to establish a genuine issue of material fact in order to be proper to submit to a jury." *Gray v. Ford Motor Co.*, No. 05 C 2236, 2011 WL 4859995, at *6 (C.D. Ill. Oct. 13, 2011).

As to the general utility of Defendants' Motrin products, the FDA estimates annual consumption rates of more than 100 million users of OTC ibuprofen. [Doc. No. 189 ¶ 16.] In the last twenty years, over six billion doses of ibuprofen have been purchased annually. [*Id.*] For the vast majority of consumers, the evidence in the record suggests that ibuprofen is a relatively effective short-term pain reliever. Defendants offer no evidence that ibuprofen provides greater relief of pain and

inflammation than any other NSAID on the market, but emphasizes that the FDA has noted that it is "in the interest of the public health to maintain in the pediatric OTC market a range of therapeutic options for the short-term relief of pain." (FDA Resp. at 9.)

The severity of the injuries suffered by those with SJS/TEN is undisputed. (Pls.' Resp. at 20; Defs.' Reply at 5.) Although both parties also agree that occurrences of SJS and TEN are rare, the parties dispute the degree of the conditions' rarity. In its response to the Citizen Petition, the FDA estimated "the overall incidences of SJS and TEN range from 1.2 to 6 per million per year and .4 to 1.2 per million per year, respectively." (FDA Resp. at 3.) Defendants argue that there is an overall incidence of one to two cases of SJS/TEN per one million persons per year from all causes. Defendants also argues that the fact that the parties dispute the exact incidences of the conditions are immaterial. (Defs.' Reply at 6.)

Plaintiffs' experts assert that SJS/TEN is substantially underreported, [Doc. No. 207, at 5-6], and maintain that "[o]thers have estimated the frequency of SJS to be as high as 49-60 cases per million." [*Id.*] Plaintiffs also argue that since the time of the FDA's determination that ibuprofen products have a very favorable risk-benefit profile in 2006, there has been a significant increase in the number of AERs of ibuprofen-related SJS and TEN cases. From 1975 until March 2005, there were 49 such AERs, (FDA Resp. at 4); since March 2005, there have been such 117 such

AERs. [Doc. No. 189 ¶ 42.][12] Defendants cite a review conducted in 2006 by Benefit Risk Management, a subsidiary of Johnson & Johnson–which specifically examined the increase in SJS/TEN AERs related to ibuprofen in 2005 and part of 2006–for the proposition that the increase in AERs was "the result of stimulated reporting, not a safety issue," and that the reports were stimulated by media attention, the FDA's labeling changes, and litigation. [*Id.* ¶ 41]; (Kuffner Decl. ¶ 8.) But, as Plaintiffs point out, a jury could draw a different conclusion based on the increase in AERs, and a jury could reasonably determine that a finding of "stimulated reporting" does not preclude the possibility that there is a safety problem with Defendants' products.

As to compliance with governmental regulations, Defendants maintain that their Motrin products are FDA-approved, the FDA has regulated OTC Motrin for nearly thirty years, and the warnings on the products used by Plaintiffs were authored by the FDA and directed by the FDA to be used on all NSAID products. (Defs.' Reply at 6.) Plaintiffs argue that the FDA is not fully aware of the most current information regarding the risk of SJS and TEN from ibuprofen, and that Defendants are not in compliance with FDA regulations because: (1) McNeil has a history of submitting safety data about SJS/TEN in a manner that conceals the

[12] Defendants maintain that many of the report forms are duplicate reports for a single adverse event. Once duplicates are accounted for, they say, there are 97 unique individual adverse events. [Doc. No. 189 ¶ 42.] Of these 97 adverse events, Defendants claim that no more than 83 of them were reported to McNeil between June 2005 and June 2011. (Id. ¶ 46.)

risk, [Doc. No. 207 ¶ 47]; and (2) McNeil has not performed a safety signal analysis regarding the risk of SJS/TEN from ibuprofen for the FDA, (Pls.' Resp. at 23). As discussed in more detail above, Plaintiff has failed to show sufficient evidence of Defendants' noncompliance.

Regarding the warnings accompanying the product, the instructions and warnings that are on Defendants' OTC Motrin products are those that were required of all OTC NSAIDs by the FDA in 2005. [Doc. No. 124 ¶ 36.] Plaintiffs complain that the label does not adequately warn users of the dangers of the product, but the label warns of serious allergic reactions and identifies a variety of circumstances under which a user should stop use and seek medical treatment. [*Id.*]

In terms of alternatives, Plaintiffs claim that dexibuprofen is a safer alternative to Defendants' ibuprofen products. Defendants argue that dexibuprofen is not available as an approved drug in the United States, and therefore that it cannot qualify as an available design substitute for Defendants' ibuprofen products. (Defs.' Mot. for Summ. J. at 23.) Plaintiffs claim that while the FDA denied approval for dexibuprofen in 1993, that was "long before publication of the literature relied on by Dr. Plunkett showing that dexibuprofen has a good safety record." (Pls.' Resp. at 25.) Plaintiffs emphasize that Defendants' expert Dr. Weisman has testified that he believes dexibuprofen is safe for OTC sale in the United States, and that nothing has stopped Defendants from performing a clinical trial and applying for dexibuprofen approval from the FDA. (*Id.* at 25-26.)

Neither party devotes much analysis to the legal question of whether a non-approved drug may be considered an available design substitute under these or similar circumstances. Defendants cite *Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561 (E.D. Pa. 2011), where the court held that "[t]here exists no FDA-approved alternative form of ibuprofen, meaning there is no available alternative design of the drug for defendants to adopt." *Id.* at 573.[13] In response, Plaintiffs cite *Madden v. Wyeth*, No. 3-03-CV-0167-BD, 2005 WL 2278081 (N.D. Tex. Sept. 14, 2005),[14] where the court came to the opposite conclusion: "[t]hat the FDA has not approved dexibuprofen for use in the United States is not dispositive as to whether the drug constitutes a safer alternative design." *Id.* at *2. The most applicable and cogent reasoning on the subject seems to come from a case cited in *Madden*: *Jones v. Lederle Labs.*, 695 F. Supp. 700 (E.D.N.Y. 1988). There, the plaintiff presented evidence that while an allegedly safer drug was not approved by the FDA at the

[13] Defendants also cite *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839 (Sup. Ct. 2003); *Ackley v. Wyeth Labs., Inc.*, 919 F.2d 397 (6th Cir. 1990); *Pease v. Am. Cyanamid Co.*, 795 F. Supp. 755 (D. Md. 1992); *Jones v. Lederle Labs.*, 785 F. Supp. 1123 (E.D.N.Y. 1992) for the same proposition, but all of those cases–except for *Militrano*–actually seem to stand for the proposition that it is possible for a non-approved drug to be considered as an available alternative so long as the plaintiff presents sufficient evidence that the defendant could have manufactured–and that the FDA would have licensed–the alternative drug by the time the allegedly injury-causing drug was manufactured. *See Ackley*, 919 F.2d at 400; *Pease*, 795 F. Supp. at 760; *Jones*, 785 F. Supp. at 1126.

[14] Plaintiffs also cite *Lofton v. McNeil Consumer & Specialty Pharm.*, 682 F. Supp. 2d 662 (N.D. Tex. 2010) where the court determined that the plaintiffs' experts' opinion regarding the defective design theory– that the racemic ibuprofen found in Motrin is associated with SJS/TEN while dexibuprofen is not–was admissible and created a matter for the jury to resolve, but did not explicitly address the specific question of whether a non-approved drug may be considered an available design substitute.

time, the defendant "could have purchased the right to produce [the allegedly safer drug], and would have been able to show the FDA that it was as effective as [the other drug]." *Id.* at 707. The court concluded that the plaintiff had presented sufficient evidence to present a question of fact for the jury. *Id.* Here, the Court comes to the same conclusion. "Under the relevant statutes and regulations, the FDA decides whether to approve for human consumption drugs submitted by private parties." *Id*. Plaintiff has offered sufficient evidence that Defendants could have applied for FDA approval of dexibuprofen and been successful.

Defendants also argue that there is no evidence that dexibuprofen is safer than ibuprofen. However, Dr. Plunkett asserts that dexibuprofen is safer because it is a pure form of ibuprofen, (S+)- ibuprofen, while the ibuprofen sold by Defendants is a racemic mixture of two isomers, (S+)- ibuprofen and (R-)- ibuprofen. (Plunkett Rep. ¶¶ 13, 15.) Dr. Plunkett also claims that the safety and effectiveness of (S+)- ibuprofen has been established by its registration and marketing in Europe, and by clinical data demonstrating that (S+)- ibuprofen can be given at a lower dose and produce similar effectiveness with less side effects than racemic ibuprofen. (*Id.* ¶ 15.)

Plaintiffs also claim that acetaminophen is a safer alternative to Defendants' ibuprofen products. Plaintiff's rely on Dr. Plunkett's testimony, and McNeil's own statements claiming that acetaminophen has a more favorable safety profile than ibuprofen. (Pl.s' Resp., at 26-27.) Defendants contend that acetaminophen fails to qualify as an "alternative design" because it is an entirely different product with

different chemical composition and different pharmacodynamic and pharmacokinetic properties, different indications, efficacy properties, safety profile and tolerability. (Defs.' Mot. for Summ. J. at 24.) Defendants cite *Brockert v. Wyeth*, 287 S.W.3d 760 (Tex. Ct. App. 2009), for the proposition that "a plaintiff cannot prove design defect by claiming that defendant should have sold an entirely different product." *Id.* at 770 (citing *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)). While the Court is somewhat sympathetic to Defendants' argument, it is based on an interpretation of Texas' state law, which is not applicable here; Defendants do not suggest that the courts of Illinois have adopted similar reasoning.

Defendants also argue that acetaminophen fails to qualify as an alternative design because there are risks associated with acetaminophen that are not associated with ibuprofen. "It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also introduce into the product other dangers of equal or greater magnitude." *Jablonski*, at 1158 (quoting Restatement (Third) of Torts: Prod. Liab. § 2 cmt. f (1998)). While Defendants have shown that acetaminophen poses risks of liver toxicity that ibuprofen does not, (*see* Plunkett Dep. at 117:25-119:14), and the FDA has recognized that other drugs can also be associated with life-threatening events, (*see* FDA Resp. at 9), Defendants have not argued that the risks of acetaminophen constitute "dangers of equal or greater magnitude." Restatement (Third) of Torts: Prod. Liab. § 2 cmt. f (1998). A material issue of fact exists on whether

acetaminophen constitutes a safer alternative design that was available and feasible at the time the product was manufactured.

The consumer expectations test is met with "'evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.'" *Mikolajczyk*, 901 N.E.2d at 336 (quoting *Lamkin v. Towner*, 563 N.E.2d 449, 457 (Ill. 1990)). "No evidence of ordinary consumer expectations is required, because the members of the jury may rely on their own experiences to determine what an ordinary consumer would expect." *Id.* at 352 (citing *Mele v. Howmedia, Inc.*, 808 N.E.2d 1026, 1037 (Ill. 2004)). Plaintiffs' claim that their evidence shows that an ordinary consumer would not expect an OTC pain reliever to cause the kind of severe injuries suffered by Blane and Mariam. (Pls.' Resp. at 17-18.) Plaintiffs also rely on expert testimony asserting that drugs sold over the counter are presumed to satisfy a higher safety standard than prescription drugs, and that such products are assumed to be safe based on their availability without a prescription. (*Id.* at 18-19) (citing Plunkett Rep. ¶ 34).

Defendants argue that consumer expectations must be judged in the context of the product's labeling. (Defs.' Reply at 11.) Defendants claim that the ordinary consumer cannot reasonably assume that OTC ibuprofen is always safe because the label plainly says otherwise. (*Id.*) The parties dispute the very nature of the ordinary consumer's expectations, and a jury is uniquely equipped to decide such an issue.

After a careful balancing of relevant factors, it is clear that Plaintiffs have produced enough evidence to establish a genuine issue of material fact.

4. Plaintiffs' Strict Liability Failure to Warn Claim (Count II)

Both parties agree that "a failure to warn of a product's dangerous propensities may serve as the basis for holding a manufacturer or seller strictly liable in tort," *Woodill v. Parke Davis & Co.*, 402 N.E.2d 194, 196 (1980), and that a product may be found to be unreasonably dangerous due to the absence of an adequate warning. *Mikolajczyk*, 901 N.E.2d at 339. Further, it is undisputed that a manufacturer has a duty to warn about the dangers of its product of which it knew or should have known. *Smith v. Eli Lilly*, 560 N.E.2d 324, 344 (Ill. 1990). Despite this agreement, Defendants maintain that summary judgment should be granted on Plaintiffs' failure to warn claim.

Defendants argue that "[g]iven the FDA's determination that these warnings are adequate (and preferable, from a public policy standpoint, to those plaintiffs seek to have a jury require), McNeil had no duty to further warn of SJS/TEN, *as a matter of Illinois tort law*." (Defs.' Mot. for Summ. J., at 30.) Defendants maintain that their position is not a revival of the preemption argument that this Court has already rejected. (Defs.' Reply at 15.) Defendants' arguments are unpersuasive.

First, Defendants initial two arguments *are* merely rehashed preemption arguments. This Court's January 9, 2012 Memorandum Opinion and Order denying Defendants' motion for summary judgment based on preemption forecloses

Defendants' position. (*See* Mem. Op. & Order, Jan. 9, 2012 [Doc. No. 164].) Secondly, Defendants' third argument–that the largest, most comprehensive, and most recent epidemiology study found no significant statistical association between ibuprofen and SJS/TEN–does not yield the conclusion that Defendants' warnings are adequate as a matter of law. Generally speaking, causation remains a disputed issue. More specifically, Plaintiffs claim that the study referenced by Defendants, the EUROSCAR 2008 epidemiology study, fails to negate the findings of the 2003 SCAR epidemiology study (finding that ibuprofen had significantly increased risks of SJS and TEN) because the more recent study "failed to examine the data based on duration of use" and utilized an exposure window that was narrower than the 2003 study. [Doc. No. 207, at 10-11.] Plaintiffs also argue that the increase in AERs after 2005 demonstrate that the association between ibuprofen and SJS/TEN is stronger than others who had evaluated the information available at the time thought before the increase occurred.

Illinois tort law does not bar a finding of liability based on a potential inconsistency with a decision of a federal agency. Even if it did, Defendants have not demonstrated that a finding of liability would result in such an inconsistency in this case. Additionally, a jury is required to decide the parties' disputes regarding causation. Because a reasonable jury could determine that Defendants' failure to include the risk and/or consequences of SJS/TEN on the labels of their Motrin products rendered the warnings inadequate, summary judgment on Plaintiffs' failure to warn claim is inappropriate.

5. Plaintiffs' Negligence Claim (Count III)

A negligence claim in a product liability action is based upon fundamental concepts of common law negligence: a plaintiff "must establish the existence of a duty, a breach of that duty, an injury that was proximately caused by that breach, and damages." *Jablonski*, 955 N.E.2d at 1153-53. The manufacturer has a duty to design a reasonably safe product, *id.* at 1154, and the manufacturer has a duty to warn of known or foreseeable risks. *Woodill*, 402 N.E.2d at 198. To determine whether reasonable care was used in designing the product, Illinois law applies the same risk-benefit balancing used to determine whether the product is unreasonably dangerous. *Jablonski*, 955 N.E.2d at 1154-55. As is the case with strict liability design defect claims, courts must conduct an initial balancing and make the threshold determination of whether the case is a proper one to submit to a jury. *Id.* at 1155. For the same reasons that summary judgment is inappropriate on Plaintiffs' strict liability design defect claim, summary judgment is inappropriate on Plaintiffs' negligence claim to the extent that it is predicated on a lack of reasonable care in designing the products in question.

Defendants also argue that, "to the extent Plaintiffs' negligence claim is predicated on a lack of reasonable care in the product's warning and instructions, it also fails." (Defs.' Mot. for Summ. J. at 28.) Defendants re-assert the same arguments they make against Plaintiffs' strict liability failure to warn claim: "[u]nder the circumstances, there is no basis for a jury to disagree with the

conclusions of the FDA, and no basis to conclude that McNeil did not act reasonably when it did precisely what the FDA required." (*Id.*) Defendants are mistaken. Summary judgment is inappropriate on Plaintiffs' negligence claim.

6. Plaintiffs' Willful and Wanton Misconduct Claim (Count VII)

To establish the propriety of the imposition of punitive damages on a party for its alleged willful and wanton misconduct, a plaintiff must demonstrate that the offending party's conduct is "outrageous, either because the defendant's acts are done with an evil motive or because they are done with reckless indifference to the rights of others." *Loitz v. Remington Arms Co.*, 563 N.E.2d 397, 402 (Ill. 1990). "In a products liability case, a manufacturer's awareness that its product poses a danger coupled with a failure to act to reduce the risk amounts to willful and wanton misconduct." *Bastian v. TPI Corp.*, 663 F. Supp. 474, 476 (N.D. Ill. 1987). The initial decision whether punitive damages may be imposed in a particular case is a question of law, and the trial court may submit the issue to the jury only if the plaintiff has made a prima facie case for such damages. *Franz v. Calaco Dev. Corp.*, 818 N.E.2d 357, 367 (Ill. App. 2004). Here, Defendants acknowledge that McNeil was aware of the potential risk of ibuprofen-caused SJS/TEN. (Defs.' Mot. for Summ. J. at 33.) Therefore, the focus is whether this awareness was coupled with a failure to act to reduce this risk. Defendants argue that there is not enough evidence of heightened culpability to establish a basis for punitive damages. Defendants are incorrect.

Defendants say that punitive damages should be precluded because: (1) Defendants have complied with FDA regulations and Defendants' labels were specifically designed by the FDA; (2) the FDA concluded in 2006 that ibuprofen should remain on the market because of its very favorable benefit versus risk profile and that it was in the interest of the public health to maintain a range of therapeutic options for the short-term relief of pain; (3) there are no available, feasible, safer alternatives to ibuprofen; and (4) the AERs do not form a basis for punitive damages.

Defendants do not explicitly assert that compliance with FDA regulations precludes a finding that their conduct was willful and wanton; instead, they argue that "[c]ourts have recognized that compliance with regulatory standards – or even a good faith attempt to comply with such standards – is inconsistent with the evil state of mind required for an award of punitive damages." (*Id.* at 36.) However, the cases cited by Defendants either do not support such a broad claim or are distinguishable from the facts in this case. In *Kolstad v. American Dental Association*, 527 U.S. 526 (1999), the Supreme Court held that "in the punitive damages context, an employer may not be vicariously liable for the discriminatory employment decisions of managerial agents where these decisions are contrary to the employer's good faith efforts to comply with Title VII." *Id.* at 545. Besides the fact that the decision has more to do with the implications of the rules of agency than the effects of regulatory compliance, the "standards" of Title VII with which the defendant employer had in good faith attempted to comply were the same

standards he (or his employee) was guilty of violating. Here, that is not the case: compliance with FDA regulations (or a good faith effort to comply) is not the same as compliance with the standards set by Illinois tort law. Put differently, in *Kolstad*, the defendant's attempt to comply with Title VII was especially relevant because he was being sued under Title VII; here, however, Defendants are not being sued under the FDCA or any FDA regulations. Defendants' reliance on *Richards v. Michelin Tire Corp*., 21 F.3d 1048 (11th Cir. 1994) is also unavailing. There, while the court recognized that a defendant's compliance with federal regulations and industry practices is some evidence of due care, the court "decline[d] to accept the invitations of Appellant and Amici to hold that compliance with [the relevant federal regulation] precludes a finding of wantonness." *Id.* at 1059 n.2.

Defendants also argue that the FDA's conclusions in 2006 – ibuprofen should remain on the market because of its very favorable benefit versus risk profile, and it was in the interest of the public health to maintain a range of therapeutic options for the short-term relief of pain – weigh against the potential imposition of punitive damages. Again, however, while the FDA's conclusions likely constitute relevant evidence on the issue of Defendants' alleged willful and wanton conduct, they do not, as a matter of law, preclude Plaintiffs' claim from going to the jury. Furthermore, Plaintiffs assert that information that has come to light since 2006 calls the FDA's conclusions into question. Defendants claim that the increase in AERs regarding ibuprofen-related cases of SJS/TEN do not form a basis for punitive damages. Specifically, Defendants argue that, despite any increase, the ratio of

AERs to doses of ibuprofen is infinitesimal, and that AERs are merely spontaneous anecdotal reports that do not reflect a causal association. (Defs.' Mot. for Summ. J. at 39.) Regarding the former, Plaintiffs counter that adverse events are severely underreported, [Doc. No. 207 at 6], and emphasize that it is the dramatic increase in AERs, and Defendants' failure to strengthen the warning labels in the face of such an increase, that is most relevant to the issue of punitive damages. As for the latter, that AERs are anecdotal in nature does not render them meaningless. On the contrary, the FDA's response to the Citizen Petition demonstrates that the FDA relied, at least in part, on its analysis of AERs to determine the SJS/TEN risks associated with ibuprofen use. (FDA Resp. at 3, 5.) Furthermore, the FDA explains that "[p]otential signals of serious risks are normally based upon groups of AERS reports, although a single AERS report could lead to further evaluation of a potential safety issue." *Potential Signals of Serious Risks / New Safety Information Identified from the Adverse Event Reporting System (AERS)*, FOOD AND DRUG ADMINISTRATION.[15] The AERs do not, by themselves, support the imposition of punitive damages, but they do constitute a factor that the jury may reasonably consider in its punitive damages calculus.

Defendants also seem to argue that punitive damages are precluded "where there is, at worst, scientific disagreement over whether ibuprofen can cause

[15] Available online at http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/adversedrugeffects/ucm082196.htm (last updated June 12, 2012).

SJS/TEN." (Defs.' Mot. for Summ. J. at 39). However, the cases Defendants cite do not support so broad a claim and are distinguishable. In *Fornoff v. Parke Davis & Co.*, 434 N.E.2d 793 (Ill. App. 1982), the court upheld a directed verdict for the defendant on a punitive damages claim because the court could find no testimony showing that the defendant marketed the product with a reckless disregard for the safety of people who might use it. *Id.* at 803. The court explained that the "evidence showed that at least two studies questioned the use of [the drug] orally, [and that] [o]ther studies disputed such findings as did all of defendant's experts." *Id.* But the court did not hold that this disagreement alone precluded the imposition of punitive damages. *Id.* Furthermore, the product in *Fornoff* was a prescription drug – which implicated the learned intermediary doctrine – and the court emphasized that the defendant included the various conflicting views on the safety of the product in the package insert of the drug. *Id.* Here, the learned intermediary doctrine is not implicated and the product label contains no information regarding the conflicting views regarding the relationship between ibuprofen and SJS/TEN. In *Loitz*, the court noted that, "[a]t trial the parties' expert witnesses disagreed on the safety and suitability of the material used by Remington in the production of its Model 1100 shotgun barrels," 563 N.E.2d at 407, but the court did not reverse the award of punitive damages based on this factor alone.

And in *Levine*, the Supreme Court made clear that "the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting

an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570. Plaintiffs argue that Defendants were aware of the risks and consequences of SJS/TEN and that they should have requested label changes that adequately warned of them, discontinued the sale of its Motrin products, and/or utilized a safer alternative in its Motrin products.[16] Plaintiffs maintain that Defendants' failure to do so constitutes willful and wanton misconduct. Defendants' arguments, neither individually nor in the aggregate, demonstrate that a reasonable jury could not determine that Defendants' conduct was willful and wanton. As such, summary judgment on Plaintiffs' claim of willful and wanton misconduct is denied.

C. Plaintiffs' Motion for Summary Judgment

Plaintiffs argue that summary judgment should be granted on Defendants' affirmative defenses of contributory negligence and assumption of risk.

1. Defendants' Contributory Negligence Affirmative Defense

Defendants concede that Blane Newman was not contributorily negligent. Plaintiffs are entitled to summary judgment on the defense that Blane Newman's negligence contributed to his injuries.

With regard to plaintiff Mariam Khawam, Defendants argue that "[t]he jury could easily infer that Mariam acted unreasonably for a 17-year-old in abdicating

[16] Defendants also argue that there is no evidence of a safer, available, and feasible alternative to ibuprofen. As is discussed in more detail above, Defendants are incorrect.

any role in decisionmaking concerning her medical treatment." (Defs.' Resp. at 4.) However, as Plaintiffs point out, Defendants' argument is foreclosed by their own admissions: "Defendant admits that Mariam Khawam ingesting Motrin given by Anna Khawam was not unreasonable." (McNeil's Resp. to Pls.' 3rd Set of Req.'s for Admissions at 4 [Doc. No. 216-1]); (Johnson & Johnson's Resp. to Pls.' 3rd Set of Req.'s for Admissions, at 4 [Doc. No. 216-2].) Defendants' admissions are binding on the issue of the reasonableness of Mariam's conduct. *See* Fed. R. Civ. P. 36(b) ("A matter admitted under this rule is conclusively established unless the court, on motion, permits the admission to be withdrawn or amended.").

Even had Defendants' not made such an admission regarding the reasonableness of Mariam's conduct, summary judgment on the issue would be appropriate. "The degree of care to be exercised by a minor over the age of seven is that which a reasonable careful person of the same age, capacity and experience would exercise under the same or similar circumstances." *Merca v. Rhodes*, 960 N.E.2d 85, 96 (Ill. App. 2011). At seventeen, Mariam was a minor under Illinois law. 755 I.L.C.S. 5/11-1. Therefore, the standard that applies here is what a reasonable seventeen-year-old girl would do when sick with a fever and given medication by her mother. No reasonable jury could find that Mariam's ingestion of Defendants' OTC fever-reducing drug, while sick with a fever and at her mother's behest, was unreasonable.

Defendants' position regarding the contributory negligence of Debra Newman and Anna Khawam is summed up as follows:

> Defendants deny that Motrin was a cause of Plaintiffs' injuries. But if a jury disagrees, the jury could still find that the Motrin warnings were not defective and Defendants were not negligent, but Plaintiffs' parents' administration of Motrin after new symptoms developed and their children's condition worsened was the sole proximate cause of the injuries.

(Defs.' Resp. at 11.)

Defendants' position is foreclosed, however, because Defendants fail to offer any evidence that either parent's provision of one additional dose of Motrin after the appearance of new symptoms contributed to Plaintiffs' injuries.

There is no evidence that the dose of Motrin provided by the parents after new symptoms had emerged caused Blane's or Mariam's SJS/TEN. Defendants' expert Dr. Mockenhaupt opines that Blane and Mariam's TEN reactions started before the allegedly negligent doses were given. (Mockenhaupt Rep. for Newman, at 15 [Doc. No. 216-4]); (Mockenhaupt Rep. for Khawam, at 15 [Doc. No. 216-5]). There is also no evidence that after a SJS or TEN reaction has begun, an additional dose of Motrin may exacerbate an afflicted individual's condition. Therefore, even if a reasonable jury could determine that Debra Newman's and Anna Khawam's conduct was unreasonable and constituted the only *potential* negligent conduct at issue, that jury could not find that such conduct was a proximate cause of Blane or Mariam's injuries.

2. Defendants' Assumption of Risk Affirmative Defense

Defendants have alleged that "Plaintiffs knowingly and voluntarily assumed any and all risks associated with matters alleged in the Complaint." (Johnson &

Johnson's Answer at 20-21 [Doc. No. 75]); (McNeil's Answer at 20 [Doc. No. 76].) Plaintiffs maintain that Blane, Mariam and their parents were unaware of the risk of SJS/TEN and so could not have assumed the risk. "In products liability action . . . assumption of risk is a bar to recovery only if the plaintiff is aware of the product defect and voluntarily proceeds in disregard of the known danger." *Court v. Grzelinski*, 379 N.E.2d 281, 284 (Ill. 1978). Whether an individual assumed the risk of injury is fundamentally a subjective test; the relevant factors are the individual's testimony concerning his or her knowledge of the danger, as well as the individual's age, experience, knowledge and understanding, and the obviousness of the defect and the danger it poses. *Saad v. Shimano Am. Corp*., No. 98 C. 1204, 2000 WL 1036253, at *8 (N.D. Ill. June 24, 2000) (citing *Williams v. Brown Manufacturing Co.*, 261 N.E.2d 305, 312 (Ill. 1970)). "If there is some evidence from which a jury might infer plaintiff's assumption of the risk, then it is within the jury's province to determine that issue." *Cleveringa v. J.I. Case Co.*, 595 N.E.2d 1193, 1209 (Ill. App. 1992).

Defendants have not contended that Blane or Mariam assumed the risk of SJS/TEN when they consumed Defendants' products; therefore Plaintiffs are entitled to summary judgment on Defendants' assumption of risk affirmative defense as asserted against Blane and Mariam.

Defendants' argument that Debra Newman and Anna Khawam assumed the risk[17] is based primarily on the facts that both parents read the warnings and instructions on Defendants' Motrin products, that they were aware that use could lead to a "severe allergic reaction," and that they were aware of instructions which directed that users "stop use and seek medical help right away" if they suffered "severe allergic reactions," or "new symptoms appeared." (Khawam Dep. at 98:5-99:7; 103:17-104:20; 106:4-10; 110:12-14; 124:13-125:17); (Newman Dep. at 83:2-15; 83:20-84:6; 122:3-123:7). Plaintiffs argue that although both parents read the warnings on the Motrin labels, neither of them were aware that "severe allergic reaction" could include the near-fatal skin sloughing, vision impairment, and other serious bodily injuries suffered by their children. Plaintiffs maintain that the assumption of risk defense is inapplicable when the plaintiff did not know of the specific danger presented by a product, and for support, cite *Byrne v. SCM Corp.*, 538 N.E.2d 796 (Ill. 1989). In that case, although the product's warning stated that its vapors were harmful and that good ventilation should be used, the court held that the evidence did not establish that the plaintiff appreciated the actual risk involved because he had not proceeded in the face of a known danger: the warning label had not advised him what type of mask was required, the instruction to use

[17] Both Plaintiffs and Defendants agree that the assumption of risk affirmative defense applies only to Plaintiffs' claims for medical expenses. (Defs.' Resp. at 12; Pls.' Reply at 11.)

good ventilation was unclear, and there was no evidence that the plaintiff was aware the product could cause damage to the central nervous system. *Id.* at 816.

Here, the labels warned of "severe allergic reactions," including "shock," "hives," "blisters," and "rash." [Doc. No. 124 ¶ 36.] SJS/TEN is not mentioned on the label, and many of the specific consequences of SJS/TEN are not included. However, a reasonable jury could determine that Debra Newman and Anna Khawam were, because of the warnings on Defendants' products, aware of the specific *kinds* of dangers that use of the products entailed. In *Byrne*, there was not a requirement that the plaintiff be aware of the precise kind of damage to the central nervous system the product could cause, or all of the particular consequences of such damage. While it is undoubtedly true that neither parent knew about SJS/TEN specifically, a reasonable jury could find that the parents were aware that use of Motrin could cause a severe reaction characterized by rashes, hives and blisters and assumed the risk of such a reaction by giving Motrin to their children. Summary judgment on Defendants' assumption of risk affirmative defense, as asserted against Debra Newman and Anna Khawam, is denied.

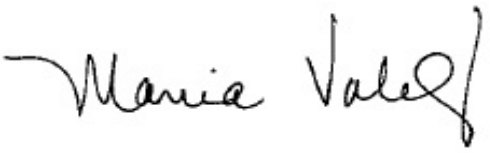
CONCLUSION

For the reasons stated above, Defendants' motion for summary judgment [Doc. No. 188] is granted in part and denied in part. Summary judgment is granted on Plaintiffs' claims of consumer fraud (Count IV) and breach of express warranty of fitness (Count V). Summary judgment is denied on Plaintiffs' claims of strict liability design defect claim (Count I), breach of implied warranty (Count VI), strict

liability failure to warn (Count II), negligence (Count III), and willful and wanton conduct (Count VII). Plaintiffs' motion for summary judgment [Doc. No. 197] is granted in part and denied in part. Summary judgment is granted on Defendants' contributory negligence affirmative defense, and Defendants' assumption of risk affirmative defense as asserted against Blane and Mariam. Summary judgment is denied on Defendants' assumption of risk affirmative defense as asserted against Debra Newman and Anna Khawam.

SO ORDERED.

ENTERED:



DATE: March 29, 2013

HON. MARIA VALDEZ
United States Magistrate Judge